K031276

JUL 2 2003

11.0 510(K) SUMMARY

DESCRIPTION

The ACLP System is an addition to Synthes' existing Anterior Cervical Vertebrae Plate System (Anterior CSLP). The ACLP System is composed of plates and screws which are made from titanium alloy Ti-6Al-7Nb (ASTM F1295). These plates attach to the anterior cervical spine with a minimum of four screws per plate.

The plates range in length to accommodate one, two, three, and four level procedures. The plates in the system are pre-lordosed to accommodate the cervical spine minimizing the need for the surgeon to manually bend the plates.

The screws in the ACLP System are 4.0mm and 4.5mm conical head screws. They are self-drilling and self-tapping in both cancellous and cortical thread profiles and are available in lengths ranging from 12mm to 16mm.

INDICATIONS

The ACLP System is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: Degenerative Disc Disease (DDD), spondylolisthesis, trauma (including fractures), spinal stenosis and tumors (primary and metastatic), failed previous fusions, pseudoarthosis, and deformity (defined as kyphosis, lordosis and scoliosis).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2003

Mr. Jonathan Gilbert
Project Manager, Regulatory Affairs
SYNTHES Spine
1230 Wilson Drive
West Chester, Pennsylvania 19380

Re: K031276
Trade Name: Synthes Anterior Cervical Locking Plate (ACLP) System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: April 21, 2003
Received: April 25, 2003

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N. Milkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 INDICATIONS FOR USE FORM

510(k) Number (if known): K031276

Device Name: Synthes Anterior Cervical Locking Plate (ACLP) System

INDICATIONS FOR USE:

The ACLP System is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: Degenerative Disc Disease (DDD), spondylolisthesis, trauma (including fractures), spinal stenosis and tumors (primary and metastatic), failed previous fusions, pseudoarthosis, and deformity (defined as kyphosis, lordosis and scoliosis).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_____
(Per 21 CFR § 801.109)

for Mark A Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031276